CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-669

Bioequivalence Review(s)

BIOEQUIVALENCY COMMENTS

ANDA: 75-669 APPLICANT: Faulding Pharmaceutical

DRUG PRODUCT: Famotidine Injection, 10 mg /mL, Preservative Free (Single Dose)

The Division of Bioequivalence has completed its review and has no further questions at this time.

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,

Dale P. Conner

Dale P. Conner, Pharm. D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

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Director, Division of Bioequivalence
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Famotidine Injection, 10 mg/mL
Preservative Free (Single Dose)
ANDA # 75-669
Reviewer: Hoainhon Nguyen
W # 75669w.799

Faulding Pharmaceutical
Cranford, NJ
Submission Date:
July 9, 1999

Review of a Waiver Request

The firm has requested a waiver from in vivo bioavailability requirements for its Famotidine Injection, 10 mg/mL, Preservative Free (Single Dose), in accordance with 21 CFR 320.22 (b) (1).

Comments:

1. The test products areparenteral solutions intended for intravenous administration.

2. The formulations of the test products are identical to that of the currently approved Pepcid® Injection, 10 mg/mL, Preservative Free (Single Dose), manufactured by Merck & Co., as shown below:

Ingredients	Test Formulation	Pepcid's Formulation
Famotidine	10 mg /mL	10 mg /mL
L-Aspartic Acid		
Mannitol		
Water for Injection		

Recommendations:

The Division of Bioequivalence agrees that the information submitted by Faulding demonstrates that its Famotidine Injection, 10 mg /mL, Preservative Free (Single Dose), falls under 21 CFR 320.22 (b) (1) of the Bioavailability/Bioequivalence Regulations. The Division of Bioequivalence recommends that the waiver of *in vivo* bioavailability study be granted. The test product,Famotidine Injection, 10 mg /mL, Preservative Free (Single Dose), is deemed bioequivalent to the currently approved Pepcid® Injection, 10 mg/mL, Preservative Free (Single Dose), manufactured by

Merck & Co..

Hoainhon Nguyen
Division of Bioequivalence
Review Branch I

RD INITIALED YHUANG for Y. C. Huang
FT INITIALED YHUANG

Concur: Date: 8/23/99
Dale P. Conner, Pharm.D.
Director, Division of Bioequivalence

ANDA #

Attachments: None